DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-10

April 30, 1998

Mr. Gerald Lustig, President
American Medical Systems
27517 Schoolcraft Road
Livonia, MI 48150

Dear Mr. Lustig:

On April 13, 1998, Investigator Deanna Lampley performed a field test of a certified diagnostic x-ray system which your firm assembled on July 31, 1997, according to Report of Assembly of a Diagnostic X-Ray System, Form FDA 2579 # C750581. The system was tested to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (Title 21, Code of Federal Regulations (CFR), section 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This field test, Test ID # GI 64157, was performed at:

DMC-HCC Woodward Detroit
22341 West 8-Mile Rd.
Detroit, MI 48219

X-Ray Control Manufacturer: [redacted]
X-Ray Control Model: [redacted]
X-Ray Control Serial #: [redacted]
Room #: Room 2

This letter confirms our telephone notification of April 23, 1998 with you regarding a serious noncompliance with the performance standard and our request that you immediately correct this violation.

The entrance exposure rate of the fluoroscopic system was measured, and was found to be [redacted] Roentgens per minute at the point where the center of the useful beam enters the patient This condition is a serious radiation health hazard and warrants your immediate attention. Title 21 CFR 1020.32(d)(1) limits the entrance exposure rate to 10 Roentgens per minute for systems with automatic exposure rate control.

In addition to the above violation, we consider the compliance status of the following item to be suspect. Please verify the compliance status of this item when you correct the previously cited item.

The difference between the x-ray field size and the image receptor size, in the plane of the image receptor, was measured to be the following for the source to image receptor distance (SID) and cassette size specified.

@SID = 43 inches (18 x 24 cm. Cassette)
Difference along table = [redacted]% of the SID
Total difference = [redacted]% of the SID

The Performance Standard requires that the difference not exceed 3.0% in any one dimension and 4.0% for the sum of the dimensions.

We request that you, as the responsible assembler, immediately investigate the deviation(s) from the performance standard cited above in accordance with 21 CFR 1003 and 1004 as follows:

1. If you determine that the deviations and/or defects are caused by improper assembly or installation, you must correct them and/or the defect(s) at no charge to the user by either repairing the system, replacing it, or refunding the cost.

2. If you determine that the deviations and/or defects are caused by the factory-based manufacturer, you must notify him of the noncompliance(s) and/or defect(s) and send documentation of such notification to this office.

3. If you can establish that the system is compliant, that the alleged deviation or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 working days of receipt of this letter.

You must report the results of your investigation and follow-up actions to this office within 30 working days of receipt of this letter. Your response should include the date that the corrective action was completed and copies of the service records and/or other supportive documents. If you do not respond within 30 working days, the FDA may consider you to be in violation of the Act, sections 538(a)(2) and 538(a)(4) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Please note that improper installation, including failure to follow installation instructions which cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under 501(c) of the Act the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct this violation can result in regulatory action being initiated by the Food and Drug and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

You should notify this office in writing, within 30 days of receipt of this letter, of the specific steps you have taken to correct the listed violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. If you have any questions with regard to the above matter, please contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155. Your response should be sent to Mr. David M. Kaszubski, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207.

Sincerely yours,

E.A. Williams /for

Raymond V. Mlecko
Acting District Director
Detroit District

cc: Ms. [redacted]
Radiology Dept.
DMC-HCC Woodland Detroit
22341 West 8-Mile Rd.
Detroit, MI 48219

cc: Mr. [redacted]
Manager, Regulatory Engineering
[redacted]